UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Stinson v. Davol, Inc., et al.*,**
Case No. 2:18-cv-01022

MOTIONS IN LIMINE OPINION & ORDER NO. 51

Defendants' Motion *in Limine* ("MIL") No. 1

Defendants C.R. Bard, Inc. and Davol, Inc. filed an omnibus Motion *in Limine* to exclude certain subjects from evidence at trial (Defendants' MIL No. 1, ECF No. 157), which is opposed by Plaintiff Aaron Stinson (ECF No. 213). For the reasons that follow, the Court **GRANTS IN PART**, **DENIES IN PART**, **DENIES IN PART AS MOOT**, and **RESERVES IN PART** Defendants' MIL No. 1.

I. Background[1]

Plaintiff's case will be tried as the third bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of an Extra-Large PerFix Plug hernia mesh device, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff's claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

In Defendants' MIL No. 1, they move to exclude nineteen categories of evidence that were addressed in one or both of the two previous bellwether cases in this MDL, *Johns v. CR Bard, Inc.,*

et al. (Case No. 18-cv-1509) and *Milanesi, et al. v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1320).

II. Standards

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would

be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III. Analysis

A. Material Safety Data Sheets ("MSDS") and Technical Data Sheets ("TDS")

Defendants seek to exclude evidence and argument related to MSDS and TDS for raw materials and chemicals. The Court addressed this issue in MIL Order No. 46 as to Plaintiff's MIL No. 2 to Exclude Evidence or Argument Concerning the Reason for Warnings on Any MSDS and Technical Data Sheets (ECF No. 262), and adopted its previous rulings from *Johns* and *Milanesi*. Evidence as to MSDS and TDS is only admissible for the purpose of notice to Defendants.

B. Devices Not at Issue

1. Non-Polypropylene Devices

Defendants seek to exclude evidence and argument concerning devices manufactured by Defendants that are not at issue in this case. The Court denied a similar motion in *Milanesi* because Defendants did not specify what evidence or testimony they wished to have excluded, nor which

devices the evidence related to. (Case No. 18-cv-1320, MIL Order No. 36, ECF No. 312.) The Court also held that:

> [T]o the extent Plaintiffs intend to introduce evidence of other Bard products that is solely meant to show that Bard "was a bad corporation," it is inadmissible under Rule 404. (ECF No. 322 at 22.) Likewise, any other-device evidence that Plaintiffs intend to use to demonstrate that Defendants knew of the health risks associated with the use of polypropylene in a medical implant must be connected to the injuries that Mr. Milanesi allegedly suffered—which, unlike in Johns, include bowel erosion, fistulae, an "infection in an abscess cavity," adhesions, and a recurrent hernia. (See Johns, ECF No. 395 at PageID #20961; Disp. Mot. Order No. 3, ECF No. 167 at PageID #13612.)

(*Id.* at PageID #17408.) The same reasoning as to propensity evidence applies here. The Court also adopts its reasoning that the use of other-device evidence must be connected to the injuries that Plaintiff allegedly suffered.

Unlike in *Johns* and *Milanesi*, Defendants identify specific devices that they seek to exclude. Defendants mention the Phasix, Phasix ST, and Phasix Plug, which are fully resorbable devices not made of polypropylene, as opposed to a permanent polypropylene device like the PerFix Plug. (ECF No. 157 at PageID #6331.) Defendants argue that any study results or complaints regarding the Phasix products could not have put Defendants on notice as to problems with polypropylene or the PerFix Plug, and the Court agrees. However, to the extent that Plaintiff's experts, such as Dr. Babensee, offer the Phasix products as a feasible alternative design, such evidence is admissible.

2. Transvaginal Mesh

Defendants next seek to exclude evidence and argument regarding transvaginal mesh devices including the Align, Avaulta, Avaulta Plus, Avaulta Solo, Ajust, Alyte, and devices that were developed but not marketed. (*Id.*) Defendants note that the FDA has reclassified surgical mesh for transvaginal repair of pelvic organ prolapse due to concerns that the mesh would erode

or become exposed through the vaginal wall or into the bladder. (*Id.* at PageID #6331–32.) According to Defendants, while the plaintiffs in *Johns* and *Milanesi* alleged injuries due to adhesions and erosion to internal organs, Plaintiff's theory of injury here is completely different. Defendants claim that allowing evidence of "devices used in different patient groups, for different indications, in different anatomical locations, with different risks" would prejudice Defendants and confuse the jury. (*Id.* at PageID #6333.)

Plaintiff points to the Court's rulings in *Johns* and *Milanesi* that the transvaginal mesh lawsuits put Defendants on notice of the risks posed by implanting Marlex polypropylene resin in the human body. (ECF No. 213 at PageID #7992 (citing Case No. 18-cv-1590, MIL Order No. 11, ECF No. 415 at PageID #22195).) Plaintiff claims that because the PerFix Plug is implanted in the pelvic area the transvaginal mesh is even more analogous here than it was in *Johns* and *Milanesi*. However, in *Johns* the Court noted the "similarities between the [transvaginal and hernia] mesh devices that indicate the devices are similar enough to be relevant to Defendants' notice." (*Id.* at PageID #22194.) The plaintiff offered expert testimony that degradation of the polypropylene in Defendants' transvaginal mesh devices resulted in adhesions, the injury at issue in that case. (*Id.* at PageID #22195.) The Court therefore found that the evidence was relevant to whether Defendants knew that Marlex polypropylene could cause adhesions. (*Id.*)

Here, Plaintiff claims that "the mechanism of failure and resulting injuries suffered by [Plaintiff] are the hallmark of the deleterious effects of polypropylene in the human body." (ECF No. 213 at PageID #7994.) He points to Dr. Babensee's citations to transvaginal mesh literature in forming her opinions, and claims that "mesh erosion and mesh migration are related concepts explaining the same mechanism." (*Id.* at PageID #7993.) In *Johns*, the plaintiff presented expert testimony linking the problems and injuries caused by transvaginal mesh and the hernia mesh

device at issue. While Plaintiff's response vaguely mentions that "both transvaginal pelvic mesh and the PerFix Plug result in high rates of chronic pain, an injury suffered by Mr. Stinson," he does not cite to any evidence or expert testimony in support of that contention. (*Id.*) Consistent with the Court's ruling in *Johns*, Plaintiff may only introduce this evidence to the extent it is connected to the injuries that Plaintiff suffered, and the Court declines to address at this time Defendants' Rule 403 arguments because they will "depend on the exact evidence offered, the questions asked during examination of witnesses, etc." (Case No. 18-cv-1590, MIL Order No. 11, ECF No. 415 at PageID #22200.)

3. Intraperitoneal Mesh

Finally, Defendants seek the exclusion of evidence and argument regarding "the risks of hernia mesh devices intended to be placed intraperitoneally because the risks associated with intraperitoneal placement of polypropylene mesh are different from those associated with devices (like the PerFix Plug) intended to be implanted preperitoneally." (ECF No. 157 at PageID #6333.) Plaintiff disagrees, and responds that "[p]olypropylene has deleterious effects on sensitive organs and structures, regardless of if the organs or structures are present in the abdomen or the pelvis." (ECF No. 213 at PageID #7994.) The above reasoning as to evidence of transvaginal mesh also applies here. Plaintiff may only introduce this evidence to the extent it is connected to the injuries that Plaintiff suffered, and the Court declines to address at this time Defendants' Rule 403 arguments because they will "depend on the exact evidence offered, the questions asked during examination of witnesses, etc." (Case No. 18-cv-1590, MIL Order No. 11, ECF No. 415 at PageID #22200.)

C. Non-Existent Duties

This issue was before the Court in *Johns* and *Milanesi*. Defendants seek to prevent Plaintiff from arguing that Defendants had a duty to train, test, or warn the general public of risks associated with the PerFix Plug. In *Milanesi* the Court granted the motion in part, agreeing that the plaintiffs had pointed to no source of a duty to warn the general public. (Case No. 18-cv-1320, MIL Order No. 42, ECF No. 318.) However, the Court adopted its ruling from *Johns* and allowed the plaintiffs to present evidence regarding ISO testing standards/guidelines (Case No. 18-cv-1320, MIL Order No. 20, ECF No. 287 at PageID #16904; Case No. 18-cv-1509, ECF No. 345 at PageID #18604), and allowed the plaintiffs to introduce evidence that, to the extent Defendants affirmatively undertook to provide training to physicians, they did so poorly (Case No. 18-cv-1320, MIL Order No. 42, ECF No. 318 at PageID #17456–57).

Consistent with the Court's rulings in *Johns* and *Milanesi*, Plaintiff may introduce evidence of the ISO testing standards/guidelines and may introduce evidence that, to the extent that Defendants affirmatively undertook to provide training to physicians, they did so poorly. Plaintiff argues that there is an exception to the learned intermediary doctrine that would require Defendants to directly warn Plaintiff of any risks of the PerFix Plug, and that Plaintiff should be permitted to introduce evidence about duties Defendants owed to the FDA, but the Court has already rejected these same arguments in *Milanesi*. (Case No. 18-cv-1320, MIL Order No. 42, ECF No. 318 at PageID #17457–58.)

D. Fraud on the FDA, Misbranding, and Violation of FDA Regulations

This issue was before the Court in *Johns* and *Milanesi*, and the Court denied in part Defendants' motions. The same analysis applies here. Plaintiff's claims do not rely solely on violations of the FDCA or FDA regulations, Plaintiff's claims are not preempted by *Buckman v.*

Plaintiffs' Legal Committee, 531 U.S. 341 (2001), and "evidence of federal requirements and whether Defendants complied with them is admissible. An instruction shall be given to the jury, explaining that the federal requirements are evidence of the duty of care and of whether Defendants' actions were reasonable, but not conclusive evidence that Defendants failed to satisfy the duty of reasonable care." (Case No. 18-cv-1509, MIL Order No. 4, ECF No. 355 at PageID #18769–72; Case No. 18-cv-1320, MIL Order No. 35, ECF No. 311.)

E. "Medical Grade" Polypropylene

This issue was before the Court in *Johns* and *Milanesi*. In both cases, the Court denied Defendants' motions and found that evidence of "medical grade" polypropylene was admissible because the term had been used in Defendants' internal documents. (Case No. 18-cv-1320, MIL Order No. 30, ECF No. 303 at PageID #17325; Case No. 18-cv-1509, MIL Order No. 2, ECF No. 331 at PageID #17885.) The Court adopts its prior rulings here.

F. Medical Device Reports and Complaints Related to Patients Other Than Plaintiff

This issue was before the Court in *Johns* and *Milanesi*. In both cases, the Court held that the plaintiffs could introduce evidence of medical device reports ("MDRs") or complaints that were substantially similar to the plaintiffs' cases, and that they could only be used to show Defendants' knowledge or state of mind and could not be used to show the device caused the plaintiffs' injuries. (Case No. 18-cv-1509, MIL Order No. 7, ECF No. 375 at PageID #20342–48; Case No. 18-cv-1320, MIL Order No. 34, ECF No. 310.) In *Johns*, the Court determined that MDRs or complaints were substantially similar when "(1) the patient had the same injury as Plaintiff—adhesions, (2) the Ventralight ST or another ST device was implanted, (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury, and (4) the repair method was laparoscopic, unless Plaintiff c[ould] show that open surgeries pose the same risk of adhesions as

laparoscopic surgeries." (Case No. 18-cv-1509, MIL Order No. 7, ECF No. 375 at PageID #20347.) In *Milanesi*, MDRs or complaints were substantially similar when "(1) the patient had the same injury as Mr. Milanesi; (2) the device at issue contained ePTFE and/or a memory coil ring; (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury; and (4) the device was placed in an intraperitoneal position." (Case No. 18-cv-1320, MIL Order No. 34, ECF No. 310 at PageID #17393.)

In this case, Defendants ask that proof of substantial similarity include that "(1) the patient had the same alleged injury as Plaintiff—chronic pain, (2) the PerFix Plug or another polypropylene-only inguinal hernia device was implanted, (3) the repair was made to a hernia or other similar inguinal soft tissue injury, and (4) the device was placed preperitoneally." (ECF No. 157 at PageID #6342.) Plaintiff claims that the Court found in the prior bellwether cases that "Defendants argue for a standard that is too exacting," and the same finding should apply here. (ECF No. 213 at PageID #8011.) However, this language is pulled out of context and is misleading as used by Plaintiff. In *Johns*, the Court found that Defendants' proposed standard was too exacting when they asked the Court to admit only MDRs or complaints where the patient had an identical medical background to the plaintiff. (Case No. 18-cv-1509, MIL Order No. 7, ECF No. 375 at PageID #20346.) Defendants ask for no such restriction here, and the standard proposed by Defendants, although adjusted to the specific facts of this case, is nearly identical to the standard the Court used in *Johns* and *Milanesi*. Plaintiff also uses language from unrelated prior MIL Orders, which do not apply here, to argue that the standard should include "any MDRs or complaints involving mesh that can or did expose bare polypropylene to sensitive tissues, organs, and structures are substantially similar," and should not be limited to inguinal hernia devices. (ECF No. 213 at PageID #8014–15.)

The Court adopts its reasoning from *Johns* and *Milanesi* and will allow evidence of substantially similar MDRs or complaints only to show Defendants' knowledge or state of mind, and not to show that the PerFix Plug caused Plaintiff's injuries. A MDR or complaint is substantially similar if (1) the patient had the same injury as Plaintiff, (2) the device at issue was a PerFix Plug or another polypropylene-only inguinal hernia device, (3) the repair was made to a hernia or other similar inguinal soft tissue injury, and (4) the device was placed preperitoneally.

G. Other Litigation

Defendants ask the Court to exclude "evidence and argument regarding (1) other lawsuits, investigations, claims, settlements, verdicts, and trials, (2) experts' roles as witnesses in other litigation, and (3) the role of counsel in other litigation." (ECF No. 157 at PageID #3642.) The Court granted in part and denied in part similar motions in *Johns* and *Milanesi*. (Case No. 18-cv-1509, MIL Order No. 3, ECF No. 332 at PageID #17888; Case No. 18-cv-1509, MIL Order No. 11, ECF No. 415 at PageID #22200–01; Case No. 18-cv-1320, MIL Order No. 37, ECF No. 313.) The Court ruled that neither party could introduce evidence of the number of cases pending in this MDL, experts' retention or fees in other cases in this MDL or other mesh litigation involving Defendants, or the number of lawyers representing either party, but they could introduce evidence of experts' fees in this case and retention and fees in other non-mesh cases, as well as prior inconsistent testimony. The Court adopts its prior ruling on those issues.

Defendants also ask the Court to preclude Plaintiff from eliciting evidence of experts' retention or fees in relation to the experts' employer. (ECF No. 157 at PageID #6343.) Defendants point to the questioning of Defendants' expert Dr. Maureen Reitman in *Milanesi*, during which the plaintiff's counsel asked how much money Dr. Reitman's employer, Exponent, had made because of the work done for polypropylene surgical mesh manufacturers. (*Id.* (citing Case No. 18-cv-

1320, ECF No. 403 at PageID #21870–71, 21867–68).) According to Defendants, that line of questioning allowed the plaintiffs to "sidestep" the Court's ruling and imply that Dr. Reitman had benefitted financially from Exponent's work in other hernia mesh litigation involving Defendants.

Plaintiff responds that Exponent's involvement in prior hernia mesh and transvaginal mesh litigation is relevant, and "Exponent is far from an unbiased institution and the jury needs to hear about biases related to Defendants' experts." (ECF No. 213 at PageID #8026.) Plaintiff asks that the determination of the admissibility of such evidence be determined at trial, and that Exponent will not be a "live issue" if Defendants do not elicit testimony about studies in which Exponent played a role. (*Id.*) The Court agrees that this issue would be better addressed in the context of trial.

H. Defendants' Conduct and Notice Evidence Post-Dating Plaintiff's Implant Surgery

Defendants ask the Court to exclude evidence and argument regarding the following evidence that postdates Plaintiff's 2015 implant surgery and 2017 explant surgery: (1) Defendants' responses to a 2017 FDA inspection, (2) the DVL-020 study, (3) labeling changes for Defendants' hernia mesh devices, and (4) a 2018 HerniaSurge publication. (ECF No. 157 at PageID #6344.)

The Court addressed the first topic, FDA inspections, in a separate order regarding Defendants' MIL No. 2 to Exclude Evidence and Argument Concerning Composix Kugel Ring Breaks, Recall, FDA Inspections, and Third-Party Audits. (MIL Order No. 48, ECF No. 264.)

In *Johns* and *Milanesi*, the Court offered a lengthy analysis and allowed limited evidence related to DVL-020, a retrospective study Defendants initiated in response to changes to European Union medical device regulations, to show that Defendants could have conducted long-term clinical testing prior to the plaintiffs' surgeries. (Case No. 18-cv-1509, MIL Order No. 5, ECF No. 359 at PageID #18796–801; Case No. 18-cv-1320, MIL Order No. 40, ECF No. 316.) The

same reasoning applies here, and the Court adopts its prior rulings. "[T]he DVL-020 is relevant and not prejudicial evidence when offered to demonstrate that Defendants could have conducted long-term clinical testing prior to Plaintiff's first surgery." (*Id.*) Defendants claim that several studies had indeed been published prior to Plaintiff's 2015 implant surgery. (ECF No. 157 at PageID #6347.) Defendants may use that information to rebut Plaintiff's arguments, but it does not make the DVL-020 inadmissible. The same reasoning applies to Defendants' argument regarding testing prior to the PerFix Plug's launch.

Defendants next ask the Court to exclude post-implant and post-explant labeling changes to Defendants' hernia mesh devices. According to Defendants, "once the PerFix Plug was designed, manufactured, warned about, and implanted, no labeling changes for any hernia mesh device would have made any difference with respect to Plaintiff's alleged injuries or implanting physician Dr. A[m]y Tan's decision to use the PerFix Plug with Plaintiff." (*Id.* at PageID #6348.) Plaintiff argues that this evidence, as well as the other evidence referenced by Defendants in this portion of their motion, is relevant to Defendants' post-sale duty to warn. Plaintiff is correct that in *Brown v. Crown Equipment Corp.*, the Supreme Judicial Court of Maine applied a continuing duty to warn. *Brown v. Crown Equip. Corp.*, 2008 ME 186, ¶ 14, 960 A.2d 1188, 1193. However, the court found that the specific facts of that case established a post-sale duty to warn, and the court "need not consider the more expansive" continuing duty to warn contained in the Restatement (Third) of Torts: Products Liability § 10. *Id.* Additionally, *Brown* was about a forklift and not an implantable medical device. As this Court noted in *Milanesi*, this case involves a complex decision regarding a medical device that had already been implanted in Plaintiff's body, and there is "absolutely no evidence in the present record suggesting that additional warnings about the [device] should have caused [the implanting surgeon] to contact [her] otherwise healthy

patients and suggest that they undergo additional medical treatment for symptoms they did not have." (Case No. 18-cv-1320, MIL Order No. 44, ECF No. 320 at PageID #17477–78 (quoting *In re Mentor Corp.*, No. 4:08-MD-2004, 2015 WL 5722799 (M.D. Ga. Sept. 29, 2015)).)

Maine has applied a continuing duty to warn with regards to a dental implant. However, that was in the context of a medical malpractice claim and "[t]his 'essential' duty arises from the special relationship between the patient, who relies heavily on the expertise of [the oral surgeon] in making decisions that may greatly impact the patient's health and well-being." *Brawn v. Oral Surgery Assocs.*, 2003 ME 11, ¶ 31, 819 A.2d 1014, 1028 (internal quotation omitted); *see also Welch v. McCarthy*, 677 A.2d 1066, 1069 (Me. 1996) ("Such failure constituted a negligent breach of the duty to warn arising by virtue of the confidential relationship between the physician and the plaintiff.").

Although the *Milanesi* case was based on Florida law, the same reasoning regarding implanted medical devices applies here. Maine's continuing duty to warn is fact-specific, and the Supreme Judicial Court declined to adopt the "expansive" standard set forth in the Restatement. This Court will therefore not expand Maine law, and instead adopts its prior ruling regarding a continuing duty to warn. (Case No. 18-cv-1320, MIL Order No. 44, ECF No. 320.) Plaintiff may not use evidence of a continuing duty to warn to show causation and liability for his injuries, but the same evidence may be admissible and relevant to show malice or reckless disregard. As it did in *Milanesi*, the Court will give a limiting instruction to the jury.

I. Marketing Materials From After Plaintiff's Implant Surgery and/or Not Relied Upon by Plaintiff's Implanting Surgeon

Similar motions were before the Court in *Johns* and *Milanesi*. In *Johns*, the Court explained that Defendants' motion was too vague and did not identify the marketing materials, and after additional briefing and oral argument, granted in part and denied in part the motion. (Case

No. 18-cv-1509, MIL Order No. 12, ECF No. 455.) In *Milanesi*, the Court again found that Defendants' motion was too vague and did not specify the types of marketing materials they wished to exclude, and denied the motion without prejudice. (Case No. 18-cv-1320, MIL Order No. 28, ECF No. 585.) In the present motion, Defendants identify the marketing materials they seek to be precluded as follows:

- Marketing materials created after Plaintiff's July 2015 implant surgery, including Technique Guides, Sell Sheets, and brochures Defendants used to market their hernia devices, including the PerFix Plug and PerFix Light Plug; and
- Discussions between Defendants' sales representatives and Dr. Tan that were not about the PerFix Plug and evidence of discussions between Defendants' sales representatives and surgeons other than Dr. Tan.

(ECF No. 157 at PageID #6351.) According to Defendants, the only claims that these marketing materials could be relevant to would be Plaintiff's negligent misrepresentation, fraud, fraudulent misrepresentation, and fraudulent concealment claims, and any marketing materials created after his implant surgery have nothing to do with those claims. (*Id.*) Plaintiff responds that the materials are relevant to his claims of warnings, negligence, and punitive damages, and are evidence of Defendants' knowledge and motive. (ECF No. 213 at PageID #8034.) Plaintiff notes that he cannot identify which specific marketing materials Dr. Tan was exposed to, and "the exact specifics of the interactions with Dr. Tan will never be fully revealed." (*Id.* at PageID #8035.)

Plaintiff claims the marketing and sales documents are directly relevant to his failure to warn claim, because they show Defendants' downplaying of warnings in order to market their products. However, if Plaintiff does not know which marketing materials Dr. Tan was exposed to, he cannot instead simply introducing *all* of Defendants' marketing materials in support of his failure to warn claim. The Court has addressed the admissibility of such evidence several times, including above as it related to devices not at issue in this case. Plaintiff may not introduce

evidence that Defendants "downplayed" warnings in other marketing materials to show that Defendants must have also done so in any marketing materials seen by Dr. Tan. Such evidence would be propensity reasoning prohibited by Federal Rule of Evidence 404(a). As to marketing materials created after Plaintiff's 2015 implant surgery, Plaintiff again raises the issue of a post-sale duty to warn. The Court addressed this issue above in Section III.H, *supra*.

J. Defendants' Financial Condition

Defendants ask the Court to, consistent with the rulings in *Johns* and *Milanesi*, exclude evidence regarding Defendants' financial condition unless and until the trial reaches a punitive damages phase. (*See* Case No. 18-cv-1509, MIL Order No. 1-A, ECF No. 330 at PageID #17883; Case No. 18-cv-1320, MIL Order No. 27, ECF No. 297.) Plaintiff opposes this portion of Defendants' motion and argues that he should be allowed to introduce evidence showing that potential testing of the PerFix Plug was not cost-prohibitive, and that the discussion of feasibility of alternative designs requires evidence of Defendants' finances during the relevant period. (ECF No. 213 at PageID #8039.)

In *In re Roundup*, the court allowed evidence of the defendant's financial condition to the extent necessary to rebut the suggestion that it would have been cost-prohibitive for the defendant to conduct studies. *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2019 WL 1371806, at *1 (N.D. Cal. Feb. 18, 2019). This Court agrees with that approach, and to the extent Defendants argue that conducting studies or using alternative designs would be cost-prohibitive, Plaintiff will be permitted to introduce evidence of the Defendants' financial condition to rebut those arguments.

K. Unrelated Investigations, Convictions, Congressional Committee Proceedings and Letters, Settlements, and Alleged Bad Acts

This issue was before the Court in *Johns* and *Milanesi*, where Defendants sought to exclude the same three types of evidence: (1) evidence of guilty pleas in relation to cardiac catheter devices,

(2) evidence of a 2013 investigation and settlement related to Defendants' brachytherapy seeds, and (3) evidence of Congressional proceedings and correspondence. In both cases, the Court denied Defendants' motions, subject to the following qualification: due to the degree of potentially unfair prejudice, neither party was permitted to refer to or offer testimony on those subjects without the prior approval of the Court. (Case No. 18-cv-1509, MIL Order No. 8, ECF No. 390 at PageID #20895–903; Case No. 18-cv-1320, MIL Order No. 21, ECF No. 288.) Although the plaintiffs in the previous two cases did not attempt to introduce the evidence at issue during trial, Defendants file their motion again out of "an abundance of caution." (ECF No. 157 at PageID #6354.) Defendants do not offer any persuasive reason as to why the Court should rule differently on these issues than it did in *Johns* and *Milanesi*.

Plaintiff requests that the Court adopt its prior rulings as to the brachytherapy seeds and Congressional proceedings, but asks that he not be required to obtain prior approval of the Court to mention the guilty pleas because they "took place at the same time [Defendants] developed the PerFix Plug." (ECF No. 213 at PageID #8040.) According to Plaintiff, the "complete reorganization of Bard's management in 1990 and massive, money-losing recalls" occurring at the company during the PerFix Plug's development are part of the "story" of the PerFix Plug, are evidence of Defendants' knowledge of inadequate procedures for meeting the standard of care, the convictions are so pervasive that they show Defendants' "routine" practices, and fairness requires Plaintiff be allowed to use the evidence to rebut Defendants' assertion that it followed FDA guidance. (*Id.*) According to Plaintiff, the guilty pleas show Defendants' abuse of the "no-510(k)" process, which is relevant because Defendants took the PerFix Plug to market under a no-510(k) rationale.

Plaintiff claims that the "ongoing turmoil" in the early 1990s influenced Defendants' decision-making process for the PerFix Plug. However, as the Court stated in *Johns*, "[e]vidence about selling off unrelated divisions appears to be inadmissible because it is irrelevant to the merits of Plaintiff's claims." (Case No. 18-cv-1509, MIL Order No. 8, ECF No. 390 at PageID #20901.) Plaintiff compares this situation to the Court's ruling in *Johns* allowing evidence "that an unrelated product was recalled—causing [Defendants] financial hardship—so the [product at issue in that case] was rushed to market." (ECF No. 213 at PageID #8043.) He argues that he should therefore be permitted in this case to introduce "evidence of the atmosphere at Bard when the PerFix Plug launched," which will provide context to the jurors. (*Id.*) However, in *Johns* the plaintiff showed that, in "an effort to rebrand the Composix Kugel, . . . Defendants focused on a speedy effort to bring ST technology (a component of the device at issue) to market to combat the financial losses from the Composix Kugel recall." (*Id.* at PageID #20963.) The Court found that the evidence pertained to how the device in that case came to market, and was therefore relevant to the reasonableness of Defendants' conduct. (*Id.*) Here, Plaintiff shows no such link between the development and marketing of the PerFix Plug and the 1994 convictions, subsequent management restructuring, and selling off of unrelated divisions of the company. Plaintiff simply asserts, without any supporting evidence, that the "ongoing turmoil at the company" must have influenced the PerFix Plug's development and release. This is not a persuasive argument as to why the Court should rule differently. The Court previously permitted, subject to prior approval of the Court, the use of evidence of the guilty pleas to contradict specific testimony that Defendants may offer in discussing their history of prioritizing patient safety, and noted that "Defendants can avoid the issue in the first place by avoiding opening the door." (ECF No. 390 at PageID #20900.) Accordingly, the Court adopts its prior rulings.

L. Corporate Intent, Motives, and Ethics

This issue was before the Court in *Johns* and *Milanesi*, and Defendants request that the Court adopt its previous rulings here. The Court explained that "although [expert] witnesses may discuss certain subjects about which they possess specialized knowledge, this does not mean that they may speculate regarding corporate intent, state of mind, and/or motivations." (Case No. 18-cv-1320, MIL Order No. 29, ECF No. 302 at PageID #17320.) As for fact witnesses, the Court held that "[i]f a corporate witness has personal knowledge of the Defendant corporations' intent or motive, such questioning may be permissible. In the event that a witness testifies on this subject matter, the Court will resolve any personal-knowledge issues during trial." (*Id.*; *see also* Case No. 18-cv-1509, MIL Order No. 6, ECF No. 366 at PageID #18930–31.) Plaintiff's response is almost identical the response that was filed to Defendants' motion in *Milanesi*. He offers no persuasive argument as to why the Court should rule differently than it did in the previous two bellwether cases. The Court therefore adopts its prior rulings.

M. Impact of Plaintiff's Alleged Injuries on Family and Friends

This issue was before the Court in *Johns* and *Milanesi*. The Court granted the motions and held that the plaintiffs could talk about what happened to them specifically, including what it did to their relationships, but he could not present evidence of any injury to non-party family or friends. (Case No. 18-cv-1320, MIL Order No. 24, ECF No. 294; Case No. 18-cv-1509, MIL Order No. 1-A, ECF No. 330 at PageID #17882.) The Court did permit the plaintiffs to present evidence of photos that included the plaintiffs' families, but clarified that it may provide a jury instruction that there is to be no consideration of any injury to any non-party friends or family. In *Milanesi*, the Court also held that the plaintiffs were to provide Defendants with copies of any such photographs

they intended to use prior to the start of trial. (Case No. 18-cv-1320, MIL Order No. 24, ECF No. 294 at Page ID #17079.) The Court adopts its prior rulings here.

N. References to *In re: E.I. du Pont de Nemours & Co. C-8 Personal Injury Litigation*

This issue was before the Court in both *Johns* and *Milanesi*. In *Johns*, the plaintiff agreed not to raise the issue at trial and Defendants' motion was denied as moot. (Case No. 18-cv-1590, MIL Order No. 9, ECF No. 393 at PageID #20948.) The plaintiffs in *Milanesi* opposed Defendants' motion; however, because there was no allegation that C-8 was at all related to the plaintiffs' injuries and there was no basis whatsoever to present such evidence or argument, the Court granted Defendants' motion, and held that if the need to reveal Defendants' expert witness's specific knowledge regarding the C-8 MSDS arose the Court would address it in the context of trial. (Case No. 18-cv-1320, MIL Order No. 23, ECF No. 290.) Here, Plaintiff responds that because Defendants do not intend to call their MSDS experts during trial, Plaintiff does not anticipate using this evidence. Therefore, this portion of Defendants' motion is denied as moot.

O. Use of Deposition Testimony and Exhibits During Opening Statements

This issue was before the Court in *Johns* and *Milanesi*. The Court held that the parties could "characterize, quote, and summarize depositions, as well as present slides with pertinent characterizations, quotes, and summaries, during opening argument. However, they [could] not quote more than one page of depositions, nor may they present deposition videos." (Case No. 18cv-1320, MIL Order No. 24, ECF No. 294 at PageID #17079–80; Case No. 18-cv-1509, MIL Order No. 6, ECF No. 366 at PageID #18931.) Defendants request that the Court adopt the same ruling here. (ECF No. 157 at PageID #6356–57.) Similar to the plaintiffs' arguments in *Milanesi*, Plaintiff claims that "this product liability action is a complex one and each case does have its

differences" (ECF No. 213 at PageID #8051) but does not point to anything in this case that would justify a different ruling. Therefore, the Court adopts its prior rulings on this issue.

P. Whistleblower Letters Referencing Dr. Tillman

This issue was before the Court in *Johns* and *Milanesi*. In *Johns*, the Court deferred ruling on whether the evidence was admissible, and the evidence ultimately was not introduced at trial. (Case No. 18-cv-1509, MIL Order No. 8, ECF No. 390 at PageID #20910–11.) In *Milanesi*, the Court granted Defendants' motion, reasoning that:

> The FDA concluded that "[t]here [was] no evidence of material violations of 21 CFR Part 10.70, other relevant rules or regulations by FDA/CDRH management," and "[t]here was no evidence of retaliation by FDA/CDRH management against complainants." (*Id.* at PageID #14031.) Additionally, in response to the whistleblower complaints, "FDA management contracted a private firm to conduct a performance audit. . . . The report issued by ICF, International favorably assessed FDA's mechanisms and abilities for settling disagreements of scientific opinion and made recommendations for further improvements to the established process." (*Id.*) Therefore, it appears that the FDA assessed the complaints for both bias and compliance with FDA procedure in rejecting the whistleblower complaints. Accordingly, the Court finds that, given that the FDA assessed the complaints for bias, the introduction of the whistleblower complaints would lead to "mini-trials" on the issue and would cause unfair prejudice.

(Case No. 18-cv-1320, MIL Order No. 33, ECF No. 309 at PageID #17385–86.) Plaintiff opposes Defendants' motion and argues that, in addition to the arguments raised by the plaintiffs in *Johns* and *Milanesi*, the evidence is relevant to Dr. Tillman's credibility as a regulatory expert. (ECF No. 213 at PageID #8053.) However, Plaintiff's response does not focus on the whistleblower letters and instead reiterates his arguments in support of excluding the Abbott warning letters related to Plaintiff's expert Dr. Beatrice. (*Id.*; *see* ECF No. 178.) Plaintiff does not point to anything in this case that justifies a different ruling than the Court issued in *Milanesi*, and the Court therefore adopts its prior ruling granting Defendants' motion.

Q. Polypropylene Degradation

This issue was before the Court in *Milanesi*. The Court denied the motion, explaining that polypropylene degradation was a fundamental theory of the plaintiffs' case and their experts offered admissible opinions that explained why polypropylene degradation and exposure to bare polypropylene were problematic. (Case No. 18-cv-1320, MIL Order No. 19, ECF No. 286.) Defendants anticipate that the Court will issue a similar ruling here, but file the motion to preserve their arguments. (ECF No. 157 at PageID #6358.) In this case, Plaintiff's experts also offer admissible opinions about the degradation of polypropylene and its relevance to Plaintiff's injuries. (*See* EMO No. 28, ECF No. 254.) Therefore, the Court adopts its prior ruling and Defendants' motion is denied.

R. Alleged Injuries of Others

In *Milanesi*, the Court determined that this issue had also been raised in Defendants' motions *in limine* to exclude complications and defects that did not occur in this case, and to exclude medical device reports and complaints related to other patients. (Case No. 18-cv-1320, MIL Order No. 41, ECF No. 317.) In the present motion, Defendants disagree and argue that the issues are separate and distinct. (ECF No. 157 at PageID #6360–61.) According to Defendants, their motion to exclude evidence of alleged injuries of others differs from their other motions, and seeks to exclude "vague reference[s] to others who have experienced complications as a result of mesh devices, suggesting that Plaintiff is just one of many 'victims' of Defendants' alleged misconduct." (*Id.* at PageID #6361.) Defendants point to statements from the trial in *Johns* from the plaintiff's counsel, such as that the plaintiff was just "but one star in the night sky," and ask the Court to exclude other such hyperbole as unfairly prejudicial. (*Id.* (citing Case No. 18-cv-1509, ECF No. 579 at PageID #32506).)

Plaintiff responds that Defendants' motion should be denied as it was in *Milanesi*, and that evidence of injuries to other patients caused by the PerFix Plug is relevant to notice, knowledge, and general causation. (ECF No. 213 at PageID #5058–60.) The Court has already explained in Section III.F, *supra*, that evidence of others' injuries in the form of substantially similar medical device reports, complaints, and adverse event reports is admissible to show notice or knowledge, but not to show that the PerFix Plug caused Plaintiff's injuries. However, in ruling on Plaintiff's MIL No. 7, the Court held that a "counsel-created, post-hoc adverse event rate to be used during argument . . . would unduly prejudice Plaintiff and mislead the jury." (MIL Order No. 46, ECF No. 262 at PageID #9682–84.) That ruling applies just as much to Plaintiff's counsel as it does to Defendants' counsel. Plaintiff will "only be permitted to introduce [alleged injuries of others] through a qualified witness who [i]s subject to vigorous cross examination." (*Id.*)

S. Alleged Improper Failure to Obtain 510(k) Clearance

This issue was before the Court in *Milanesi*. The plaintiffs in that case stated that they had no intention of arguing that the product at issue was on the market illegally, and the Court denied Defendants' motion, noting that the plaintiffs were simply disagreeing that Defendants utilized the appropriate route to bring the device to market. (Case No. 18-cv-1320, MIL Order No. 15, ECF No. 276.) Defendants ask that Plaintiff "not be permitted to argue that the PerFix Plug has ever been on the market illegally." (ECF No. 157 at PageID #6362.) In his response, Plaintiff explains that he does not intend to argue that the PerFix Plug was on the market illegally, but "rather to introduce the relevant evidence related to [Defendants'] conduct and decision to bring the PerFix Plug to market without 510(k) clearance." (ECF No. 213 at PageID #8061.) The analysis in *Milanesi* applies here, and the Court adopts its prior ruling. As to the 2009 FDA correspondence, the Court addressed this issue in its ruling on Plaintiff's MIL No. 3 to Exclude Evidence that the

PerFix Plug was Approved or Cleared by the FDA, and FDA 2009 Correspondence and Testimony as to FDA's Intent With Respect to Such Correspondence. (MIL Order No. 48, ECF No. 264.)

IV. Conclusion

For the reasons set forth above, Defendants' MIL No. 1 (ECF No. 157) is **GRANTED IN PART**, **DENIED IN PART**, **DENIED IN PART AS MOOT**, and **RESERVED IN PART**.

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

6/12/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE